UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

LESLIE WHITE, Plaintiff, v. ETHICON, INC., Defendant.	CASE NO. C20-0952 BHS ORDER ON DEFENDANT'S SUPPLEMENTAL MOTION FOR SUMMARY JUDGMENT

This matter comes before the Court on Defendant Ethicon, Inc.'s supplemental motion for summary judgment. Dkt. 99. The Court has considered the briefing filed in support of and in opposition to the motion and the remainder of the file and hereby rules as follows.

I. PROCEDURAL HISTORY

This case originated in the MDL *In re Ethicon, Inc. Products Liability Litigation*, MDL No. 2327, located in the Southern District of West Virginia. Dkt. 4. Plaintiff Leslie White brings claims against Ethicon arising out of the surgical implantation of its product TVT-Exact, a polypropylene mesh implant. *Id.*

Prior to the case's transfer to this Court, Ethicon moved for partial summary judgment. Dkt. 35. In June 2020, the case was transferred to this Court from the Southern District of West Virginia. Dkt. 56. The parties then stipulated to dismiss with prejudice nine of White's claims and agreed that Ethicon's motion for partial summary judgment was moot. Dkt. 71. White's unconceded claims are: Negligent Design Defect, Strict Liability – Failure to Warn, Strict Liability – Design Defect, Common Law Fraud, Fraudulent Concealment, Constructive Fraud, Punitive Damages, and Discovery Rule and Tolling. *Id.* Ethicon moves for summary judgment on these remaining claims. Dkt. 99.

II. FACTUAL BACKGROUND

In February 2014, White was surgically implanted with TVT-Exact to treat her stress urinary incontinence ("SUI") in Edmonds, Washington. Dkt. 4, ¶¶ 8–11; Dkt. 114-1, Deposition of Douglas Grier ("Grier Depo."), at 7:17–20. Dr. Douglas Grier performed White's surgery to implant the device. Dkt. 4, ¶ 12.

Dr. Grier has been a board certified urologist since 2000 and has used over 1,500 TVT products to treat SUI over the past eighteen years. Grier Depo. at 16:3–9; 10:12–15. Dr. Grier has also surgically removed mesh products before, commonly referred to as mesh revisions, but testified that he still uses TVT products. *Id.* at 94:19–22; 10:16–17. Prior to White's surgery in 2014, Dr. Grier served as a lecturer or teacher to surgeons regarding the use of TVT products, including the TVT-Exact. *Id.* at 19:7–20. Dr. Grier was hired by Ethicon for these courses or seminars over a period of fourteen years. *Id.* at 79:13–25.

Dr. Grier testified that, prior to 2014, he was generally aware of the potential risks and complications associated with TVT implants, including acute and chronic pain with intercourse, vaginal scarring, infection, urinary problems, fistula formation, neuromuscular problems, recurrence, erosion, exposure, and extrusion. *See, e.g.*, *id.* at 32:15–33:13. But despite those risks, Dr. Grier considered the TVT-Exact to be a safe and effective product and "the gold standard treatment" for SUI. *Id.* at 11:1–16. Furthermore, Dr. Grier testified that he stands by his decision to use the TVT-Exact to treat White's SUI. *See id.* at 92:24–93:16.

The TVT-Exact product itself was accompanied by a package insert commonly referred to as "Instructions for Use" ("IFU"). As explained by Dr. Grier, an IFU "is a surgical description of the device and its application, but it's not intended to be comprehensive and it's certainly not intended to discuss the indications, risks, or possible complications of the procedure to the patient." *Id.* at 61:8–13. Dr. Grier further testified that he did not rely upon the IFU accompanying White's TVT-Exact in deciding what information to provide her prior to surgery. *Id.* at 61:3–6. White asserts that the TVT-Exact IFU did not include all known risks and significantly downplayed the frequency or severity of the risks and/or adverse reactions. Dkt. 113 at 6 (citing Dkt. 114-6 at 42–43).

TVT-Exact products are made with polypropylene mesh (also referred to as prolene mesh), which White argues is inadequate for permanent implantation. White's case-specific expert, Dr. Bruce Rosenzweig, opines that the characteristics of polypropylene mesh make it unsuitable for permanent implantation, including: "(1) excessive rigidity of laser-cut mesh; (2) degradation of the mesh; (3) chronic foreign

body reaction; (4) infections and bio-films; (5) fibrotic bridging leading to scar plate formation and mesh encapsulation; and (6) shrinkage/contraction of the encapsulated mesh." Dkt. 114-6 at 12. White further asserts that prolene mesh is not suitable for permanent human implantation because the polypropylene resin used to manufacture the mesh products is incompatible with strong oxizers and/or strong oxidizing agents.[1] Dkt 113 at 6–7 (citing Dkt. 114-7 at 4, Dkt. 114-8 at 3). Rosenzweig opines that it is well known to physicians with expertise in the pelvic floor that "vaginal and perivaginal tissues are ready sources for peroxide," which is a strong oxidizing agent. Dkt. 114-6 at 16. Dr. Grier testified that he would not use TVT implants if polypropylene was found to not be suitable for human implantation. *See* Grier Depo. at 99:23–100:11.

White additionally represents that alternative, safer designs existed. Dkt. 113 at 9–10. Her general expert, Scott Guelcher, opines that dermal allografts (medical products that have been prepared from human cadaveric fascia and human dermis) and polyvinylidene fluoride ("PVDF") do not present the same chronic complications associated with TVT mesh and were available when the TVT device was first commercialized. Dkt. 114-10 at 21–23.

[1] White relies upon two Material Safety Data Sheets ("MSDS") released by Ethicon's polypropylene resin manufacturer to support this assertion. Ethicon objects, arguing that the MSDSs were issued by non-party material suppliers pursuant to Occupational Safety and Health Administration regulations pertaining to the handling of raw materials. Dkt. 115 at 4; *see also* 29 C.F.R. § 1910.1200(b)(1). Ethicon thus argues the MSDSs are inadmissible because they have no relationship to or bearing upon Ethicon's finished medical devices.

White alleges that she suffered injuries because of her TVT-Exact implant and thus brings claims under the Washington Products Liability Act ("WPLA"), RCW 7.72, *et seq.*, among others.

III. DISCUSSION

Ethicon moves for summary judgment on White's remaining claims. Dkt. 99. In response, White asserts that she is only pursuing her WPLA failure to warn claim, WPLA design defect claim, and punitive damages and concedes the dismissal of her other claims. Dkt. 113 at 2.

A. Summary Judgment Standard

Summary judgment is proper only if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party is entitled to judgment as a matter of law when the nonmoving party fails to make a sufficient showing on an essential element of a claim in the case on which the nonmoving party has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). There is no genuine issue of fact for trial where the record, taken as a whole, could not lead a rational trier of fact to find for the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (nonmoving party must present specific, significant probative evidence, not simply "some metaphysical doubt"). Conversely, a genuine dispute over a material fact exists if there is sufficient evidence supporting the claimed factual dispute, requiring a judge or jury to resolve the differing

versions of the truth. *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 253 (1986); *T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

The determination of the existence of a material fact is often a close question. The Court must consider the substantive evidentiary burden that the nonmoving party must meet at trial—e.g., a preponderance of the evidence in most civil cases. *Anderson*, 477 U.S. at 254; *T.W. Elec. Serv., Inc*., 809 F.2d at 630. The Court must resolve any factual issues of controversy in favor of the nonmoving party only when the facts specifically attested by that party contradict facts specifically attested by the moving party. The nonmoving party may not merely state that it will discredit the moving party's evidence at trial, in the hopes that evidence can be developed at trial to support the claim. *T.W. Elec. Serv., Inc*., 809 F.2d at 630 (relying on *Anderson*, 477 U.S. at 255). Conclusory, nonspecific statements in affidavits are not sufficient, and missing facts will not be presumed. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888–89 (1990).

B. Strict Liability – Failure to Warn

The WPLA permits recovery "if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was . . . not reasonably safe because adequate warnings or instructions were not provided." RCW 7.72.030(1). To prevail on a failure to warn claim, a plaintiff must show that (1) the defendant failed to sufficiently warn, (2) the plaintiff suffered damages, and (3) the defendant's failure to sufficiently warn of the dangers was a proximate cause of the plaintiff's damages. *See, e.g., Little v. PPG Indus., Inc.*, 19 Wn. App. 812, 818 n.3 (1978) (approving the Restatement (Second) of Torts' recitation of the elements). However, in the context of

medical failure to warn claims, the duty of the manufacturer to warn is satisfied if the manufacturer gives adequate warning to the physician who prescribes or implants the product. *Terhune v. A.H. Robins Co.*, 90 Wn.2d 9, 13 (1978).

A failure to warn claim is assessed either under the consumer expectations test or the risk-utility test. As to the former, "the trier of fact shall consider whether the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer," here the implanting physician. RCW 7.72.030(3); *see also O'Connell v. MacNeil Wash Sys. Ltd.*, 2 Wn. App. 2d 238, 251 (2017) ("The consumer expectation test is more direct. Under this test, the plaintiff must show the product was more dangerous than the ordinary consumer would expect."). As to the latter, "the trier of fact must balance the likelihood that the product would cause the harm complained of, and the seriousness of that harm, against the burden on the manufacturer of providing an adequate warning." *Ayers v. Johnson & Johnson Baby Prods. Co.*, 117 Wn.2d 747, 765 (1991). White argues that she has a viable failure to warn claim under either test.

As a preliminary matter, White asserts that is Ethicon's burden to show that "no reasonable prescribing physician apprised of the label's contents would be unaware of the risks specific to that medical device." Dkt. 113 at 12 (quoting *Falsberg v. GlaxoSmithKline, PLC*, 176 Wn. App. 1019, at *4 (2013) (internal quotation and alternations omitted)). White's reliance on the unpublished opinion for this proposition is misplaced. *Falsberg* reviewed whether a prescription label was adequate as a matter of law under Restatement (Second) of Torts § 402A, comment k. 176 Wn. App. 1019, at *2–3. Here, Ethicon is not specifically arguing that the TVT-Exact's IFU was adequate as

a matter of law but rather that White cannot establish proximate cause. *See* Dkt. 99 at 7–10. It is not Ethicon's burden to establish that its labeling was adequate—it is White's burden to show that Ethicon's warnings were inadequate.

Ethicon argues that, under either failure to warn theory, White has failed to create a triable issue that any actionable failure to warn proximately caused her injuries. In order to prove causation, a plaintiff must show that the implanting physician was aware of the alleged inadequate warning made by the defendant. *See Cutter v. Ethicon, Inc.*, No. 5:19-443-DCR, 2020 WL 109809, at *8 (E.D. Ky. Jan. 9. 2020) ("Dr. Guiler testified that he did not consult these materials to obtain information about the risks of implanting the Prolift device in Jenesta and, in fact, has never relied on them for such information."). And a plaintiff must also show that the physician would have acted differently had he been given an adequate warning. *See Contreras v. Bos. Sci. Corp.*, No. 2:12-cv-03745, 2016 WL 1436682, at *4 (S.D. W. Va. Apr. 11, 2016) ("Here, the plaintiffs have not provided any citations to the record showing that Dr. Baker, the implanting physician, would have taken a different course of action even if she had been given an adequate warning."); *Fulgenzi v. PLIVA*, 140 F. Supp. 3d 637, 649 (N.D. Ohio 2015) ("The undisputed facts in the record establish that plaintiff's physicians did not ever read, let alone rely on, PLIVA's inadequate 2004 warning."); *Higgins v. Ethicon, Inc.*, No. 2:12-cv-01365, 2017 WL 2813144, at *3 (S.D. W. Va. Mar. 30, 2017) (granting summary judgment on a Texas law failure to warn claim because "[t]he plaintiffs have failed to present any testimonial or other evidence that Dr. Anhalt would not have used or prescribed the TVT-S to treat Ms. Higgins had he received a different warning.").

Ethicon argues that Dr. Grier, White's implanting physician, was aware of the specific risks and injuries that White's case-specific expert attributes to her TVT-Exact implant. It further asserts that Dr. Grier did not rely upon the IFU in making his treatment decision for White and relied on his own knowledge gained through residency, conferences, courses, his own independent research, and his own expertise. Finally, Ethicon argues that Dr. Grier testified that he stands by his decision and that he would not have taken a different course of action if additional warnings were given to him.

White responds and argues that she can establish causation because Dr. Grier testified that he was not aware that polypropylene is not safe for permanent human implantation, because Dr. Grier does in fact rely on Ethicon for information with respect to the TVT-Exact, and because he testified that he would have acted differently if he had been warned that polypropylene was not safe for permanent human implantation. Dkt. 113 at 14–15. She additionally argues that the reasonableness and credibility of Dr. Grier is an issue for the jury. *Id.* at 15–17.

White's theory that polypropylene is not safe for permanent human implantation is largely supported by the MSDSs released by Ethicon's polypropylene resin manufacturer, *see* Dkts. 114-7, Dkt. 114-8, and her experts' opinions derived from the MSDSs. Ethicon argues that the MSDSs are irrelevant, inadmissible, and immaterial because the safety data sheets have no relationship to or bearing upon its finished medical devices. The MSDSs from other companies' materials suppliers, such as the Chevron Phillips MSDS, are irrelevant to this case. However, it is possible that the MSDSs from Ethicon's suppliers could be relevant, and the Court will thus consider the evidence.

The Court concludes that there is a question of fact as to whether Dr. Grier "would have treated the product differently and avoided the harm" if adequately warned of the risks. *Ayers By and Through Smith v. Johnson & Johnson Baby Prods. Co.*, 59 Wn. App. 287, 291 (1990). Although Dr. Grier stated in his deposition that he stands by his decision to use the TVT-Exact to treat White's SUI, *see* Grier Depo. at 92:24–93:16, he testified that he would not use TVT implants if polypropylene was found to not be suitable for human implantation, *see id*. at 99:23–100:11. Viewing the evidence in the light most favorable to White, the non-moving party, there is a logical inference that the polypropylene mesh used in White's TVT-Exact was not safe for permanent human implantation because the mesh itself is incompatible with strong oxizers. *See* Dkt. 114-7 at 4. Rosenzweig opines that that "vaginal and perivaginal tissues are ready sources for peroxide," which is a strong oxidizing agent and makes the implant not suitable for human implantation. Dkt. 114-6 at 16. It is therefore a question of fact as to whether Dr. Grier "would have treated the product differently and avoided the harm," *Ayers*, 59 Wn. App. at 291, if warned of these risks.

Furthermore, Dr. Grier testified only that he did not rely upon the IFU accompanied with White's TVT-Exact in deciding what information to provide White prior to surgery, not that he did not read or rely upon the IFU at all. *See* Grier Depo. at 61:3–6. Dr. Grier did testify he was aware of the risks and potential complications of the TVT-Exact and gained that knowledge from his personal experience and reviewing literature, among others. *See, e.g.*, *id.* at 37:12–18. But the evidence is not sufficiently clear as to whether he actually relied on Ethicon's labeling or whether he relied upon his

own knowledge in recommending the TVT-Exact to White. There are thus questions of fact as to whether Ethicon's alleged inaccurate warnings proximately caused White's harm.

Summary judgment is, therefore, DENIED as to White's Strict Liability – Failure to Warn claim.

C. Strict Liability – Design Defect

The WPLA also allows for recovery "if the claimant's harm was proximately caused by the negligence of the manufacturer in that the product was not reasonably safe as designed." RCW 7.72.030(1). To prevail in a WPLA claim for design defect, a plaintiff must show that (1) a manufacturer's product (2) not reasonably safe as designed (3) caused harm to the plaintiff. *Pagnotta v. Beall Trailers of Or., Inc.*, 99 Wn. App. 28, 36 (2000).

Like a failure to warn claim, a design defect claim under WPLA may be established either under the consumer expectations test or the risk-utility test. Under the consumer expectation standard, the plaintiff must show the product was more dangerous than the ordinary consumer would expect. *Falk v. Keene Corp.*, 113 Wn.2d 645, 655 (1989). The parties dispute whether the ordinary consumer is the prescribing physician or an ordinary physician-consumer. Under the risk-utility test, a plaintiff must show that, at the time of manufacture, "the likelihood that the product would cause plaintiff's harm or similar harms, and the seriousness of those harms, outweighs the manufacturer's burden to design a product that would have prevented those harms and any adverse effect a

practical, feasible alternative design would have on the product's usefulness." *Id.* at 654; *see also* RCW 7.72.030(1)(a).

1. Consumer Expectations Test

White argues that she has a viable design defect claim under the consumer expectations test because there is a dispute among the experts in this case as to whether the TVT-Exact was more dangerous than an ordinary physician-consumer would expect. Dkt. 113 at 18–19. Ethicon asserts that the question is only whether the TVT-Exact was more dangerous than Dr. Grier—White's implanting physician—would expect. Dkt. 99 at 13–14.

The Court agrees with White here. Based on the Court's own research, it appears that the learned intermediary doctrine under the WPLA is specific to failure to warn claims. The Washington Supreme Court in *Terhune* held that "the duty of the manufacturer to warn of dangers involved in use of a product is satisfied if he gives adequate warning to the physician who prescribes it." 90 Wn.2d at 13; *accord Estate of LaMontagne v. Bristol-Myers Squibb*, 127 Wn. App. 335, 345 (2005) (explaining that Washington has adopted the learned intermediary doctrine in addressing failure to warn WPLA claims). Design defect claims, however, consider "the ordinary consumer." RCW 7.72.030(3); *see also Falk*, 113 Wn.2d at 654 ("[T]he plaintiff may nevertheless establish manufacturer liability by showing the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer. If the product design results in a product which does not satisfy this consumer expectations standard, then the product is not reasonably safe." (internal citation omitted)). The question here is therefore whether

the TVT-Exact was unsafe to an extent beyond what would be contemplated by the ordinary, physician consumer.

White has presented evidence of six urogynecologists who will testify differently about whether the TVT-Exact was more dangerous than would be contemplated by an ordinary physician-consumer. *See* Dkt. 113 at 18–19. There is thus a question of fact as to whether the TVT-Exact was more dangerous than contemplated by the ordinary physician consumer. And even if the question was whether the TVT-Exact was more dangerous than contemplated by White's implanting physician, Dr. Grier specifically testified that he would not use TVT implants if told that polypropylene was not safe for permanent human implantation. *See* Grier Depo. at 99:23–100:11.

Summary judgment is, therefore, DENIED as to White's Strict Liability – Design Defect claim under the consumer expectations test.

2. Risk-Utility Test

White also argues that her design defect claim satisfies the risk-utility test, which requires a plaintiff to prove the existence of an alternative design that was practical and feasible and that would have prevented plaintiff's harm. *See* RCW 7.72.030(1)(a); *Ruiz-Guzman v. Amvac Chem. Corp.*, 141 Wn.2d 493, 503–05 (2000). White's general expert, Dr. Guelcher, opines that alternative designs using allografts and PVDF were available to Ethicon and are safer than the use of polypropylene. Dkt. 113 at 20 (citing Dkt. 114-10 at 23). Ethicon responds that biological allografts are not sufficiently comparable "products" for a design defect claim and that there is no FDA-approved sling made of PVDF. Dkt. 115 at 11. Ethicon also highlights that, even if the two alternate designs

suggested by Guelcher were products, White lacks a case-specific expert opinion that either alternative would have prevented her harm. The Court agrees.

Even assuming that the Court could consider biological allografts or PVDF as alternative products, White must establish causation. Expert testimony is not always required to establish causation for a design defect claim, but "[e]xpert testimony is required to establish causation when an injury involves obscure medical factors that would require an ordinary lay person to speculate or conjecture in making a finding." *Bruns v. PACCAR, Inc.*, 77 Wn. App. 201, 214 (1995) (internal citations omitted). Guelcher's expert report does not establish that "the defect more probably than not caused [White's] injuries." *Id.* at 215 (internal quotation omitted). As such, White has not created a genuine issue of material fact as to causation.[2]

Summary judgment is therefore GRANTED as to White's Strict Liability – Design Defect claim under the risk-utility test. Her design defect claim under this theory is DISMISSED with prejudice.

D. General Strict Liability – Consumer Expectations

White argues that she may assert a separate claim under the consumer expectations test even if she fails to otherwise establish a claim under the WPLA. Dkt. 113 at 21 (citing, *inter alia*, *Kirkland v. Emhart Glass S.A.*, 805 F. Supp. 2d 1072, 1081 (W.D.

[2] The Eastern District of Washington has also reached this conclusion. *See Lynch v. Ethicon, Inc.*, No. 2:20-cv-00217-SMJ, 2020 WL 5733184, at *2 (E.D. Wash. Sept. 24, 2020.) ("But without an expert opinion asserting a causal link between the general *design defects* identified by Dr. Veronikis and Lynch's injuries, Lynch has not established a genuine issue of material fact." (emphasis in original)).

Wash. 2011)). Even if a plaintiff fails to otherwise establish a claim under the WPLA, "the plaintiff may nevertheless establish manufacturer liability by showing the product was unsafe to an extent beyond that which would be contemplated by the ordinary consumer." *Falk*, 113 Wash.2d at 654.

Here, because the Court has concluded that proximate cause as to White's failure to warn claim is a question for the jury and because there are questions of fact as to whether the device was more dangerous than contemplated by an ordinary physician consumer, the Court also concludes that Ethicon is not entitled to summary judgment on any claim White may bring under RCW 7.72.030(3). Summary judgment is therefore DENIED.

E. Punitive Damages

Ethicon moves for summary judgment on White's punitive damages claim, arguing it should be dismissed because her substantive claims have been dismissed or, alternatively, because Washington law does not allow for punitive damages. Dkt. 99 at 16. White argues that under Washington's choice of law analysis her claim for damages is governed by New Jersey law, which permits punitive damages in product liability cases. Dkt. 113 at 22–25.

Ethicon did not reply to White's choice of law arguments, *see generally* Dkt. 115, and the Court has not yet considered whether punitive damages are available under New Jersey law in these product liability cases. The Court would benefit from additional briefing and therefore reserves ruling on this issue. Ethicon is granted leave to file a surreply, which is detailed in the order below.

IV. ORDER

Therefore, it is hereby **ORDERED** that Ethicon's supplemental motion for summary judgment, Dkt. 99, is **GRANTED in part** and **DENIED in part**. It is hereby further **ORDERED** that the Court **RESERVES RULING** on the availability of punitive damages. Ethicon shall file a surreply addressing White's choice of law arguments on or before **January 28, 2022**. The surreply shall not exceed 10 pages.

White's claims for Negligent Design Defect, Strict Liability – Design Defect under the risk-utility test, Common Law Fraud, Fraudulent Concealment, Constructive Fraud, and Discovery Rule and Tolling are **DISMISSED with prejudice**.

Dated this 14th day of January, 2022.

BENJAMIN H. SETTLE
United States District Judge